

## REMARKS

This response is being filed within two months of the mailing of a Final Office Action, and is intended to place the application in condition for allowance or, at least, to reduce the issues upon appeal. Entry of this response is respectfully requested, therefore.

Claims 1-18 and 29 are pending and claims 19-28 remain withdrawn from consideration. No claims are amended, canceled, or added presently.

### **(A) Rejection over Okada and Billington Should Be Withdrawn**

The sole rejection is of claims 1-18 and 29 over the combination of WO 00/58316 (equivalent to U.S. 6,458,868) to Okada *et al.* with U.S. 4,514,342 issued to Billington *et al.* Applicants respectfully traverse this rejection, incorporating by reference their previous remarks and, additionally, requesting Examiner Heincer's consideration of the fact that the skilled artisan would have had no reason to combine Okada and Billington in the manner posited in the final action.

*Hindsight Reconstruction Is Impermissible – A Lead Compound For Modification Must Be Selected Based On Prior-Art Teachings, NOT On Applicant's Disclosure*

In proffering the instant rejection, the Examiner has been guided by the Applicants' own teachings to choose particular groups from each reference, to thereby arrive at the presently claimed invention. That this approach is improper is apparent from the PTO's own rules. For instance, § 2141.01(III) of the MPEP notes that the "content of the prior art is determined at the time the invention was made to avoid hindsight," and §707.07(f) states that

...any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, *and does not include knowledge gleaned only from the applicant's disclosure*, such a reconstruction is proper.

(Emphasis added.) Similarly, the “tendency to resort to ‘hindsight’ based upon Applicant’s disclosure is often difficult to avoid due to the very nature of the examination process. However, *impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.*” MPEP § 2142 (emphasis added)

The PTO’s review court likewise has mandated that “a prima facie case of obviousness for a chemical compound...begins with the reasoned identification of a lead compound.” *Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.*, 533 F.3d 1353,1359 (Fed. Cir. 2008) (copy appended). From this perspective, substantiating a finding of obviousness can be based on structural similarity along with some “motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound.” *Id.* at 1357.

Section 2143.01 (III) of the MPEP explains that “the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” This is wholly consistent with the position taken by the Federal Circuit in *Eisai*. The prior art must form the basis for the reasons to modify a particular compound, and the prior art must provide reason to one of skill in the art to select a particular compound for modification. Neither Okada nor Billington evidences such a reason.

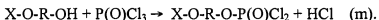
*Okada Guides The Person Of Ordinary Skill In The Art To A Phosphate Compound, Not A Phosphonate Compound*

Okada is directed to (1) an organic phosphate compound having at least one radically polymerizable double bond, (2) a dental composition thereof, (3, 4) processes for preparing (meth)acrylic acid monoester monophosphate esters from *phosphorous oxychloride*, (5) a process for preparing an organic phosphate compound from a *phosphorous oxyhalide*, and (6) a process for preparing a (meth)acrylic acid monoester monophosphate ester from a *phosphorous oxychloride*. Column 4, line 16 to Column 5, line 37. The ideals of low color and good storage stability, in view of Okada’s directives 1-6, make it clear that his invention is based upon

phosphates prepared from phosphorous oxyhalide species such as the oxychloride, or from phosphorous pentaoxide. The examples bear this out, with Okada describing the preparation of a number of phosphate compounds, such as those listed in Table 9 as compounds 1a - 4. Every example is of a compound with a single (meth)acrylate residue.

In describing the synthetic procedures to accomplish the above objectives, Okada generally describes the preparation of the phosphates as:

The reaction process is represented by the following chemical equation (m).



Wherein X-O-R-OH is a (meth)acrylic acid monoester; X is a (meth)acroyl group; and R is an organic residue having 4 to 30 carbon atoms.

Column 18, lines 34-40.

Okada repeatedly alludes to the large variability of the reactions with respect to phosphates and phosphate monomers, always, and correctly, referring to them as phosphates. For example, see column 6, line 14 - column 8, line 46. Okada also provides guidance as to “the process for preparing a phosphate monomer of the present invention...” (column 11, lines 42 & 43). Okada goes on to describe a number of processes that begin with or involve the reaction of POCl<sub>3</sub> or P<sub>2</sub>O<sub>5</sub> and that all form phosphates, not phosphonates as presently claimed. See column 11, line 44 - column 12, line 22.

The only discussion of phosphonate compounds in Okada relates to compounds 5a and 5b. Okada describes a single reaction sequence for their preparation, based on a specific reaction scheme from 2-carboxyethyl phosphonate; that is, 2-carboxyethyl phosphonate is reacted with 5-hydroxypentyl methacrylate or 10-hydroxydecyl methacrylate, to form 5a and 5b, respectively. Informed by Okada, therefore, the skill artisan would have had but a single, specific preparative

scheme for two compounds that differ merely by the length of an alkyl chain, *i.e.* pentyl and dodecyl. Both of compounds 5a and 5b contain a single (meth)acrylate residue.

Clearly, Okada emphasizes phosphate compounds, their preparation, and their preferred properties. Thus, Okada guides the skilled artisan to select a phosphate as a lead compound for modification.

*Billington Also Guides The Person Of Ordinary Skill In The Art To A Phosphate Compound, Not A Phosphonate Compound*

Similarly, Billington is directed to phosphate compounds  $[(RO)_2P(O)OR']$ , not the presently claimed phosphonates  $[(RO)_2P(O)R'']$ . In fact, Billington is silent with respect to phosphonate compounds in any context. The compounds of Billington are prepared through phosphorylation of the compounds of Formula II, by reaction with phosphorous oxychloride or phosphorous pentoxide, a methodology that is similar to Okada. Hence, like Okada, Billington guides the skilled artisan to prepare a phosphate compound.

*Okada Does Not Support The Examiner's Rationale for Combining The References*

To validate the combination of these references, the Examiner states at page 4 of the action, in lines 4 and 5, that "Okada et al. teaches that monoesters and polyesters of polyols and (meth)acrylic acid are interchangeable in terms of reactivity (12:23 to 14:20)." However, the listing referred to by the Examiner is followed in Okada at column 14, lines 23-30, by the statement that, "when the phosphate monomer according to the [Okada] invention is prepared by the process described above, there can be preferably used...a polyol compound having...4 or more carbon atoms and two or more hydroxyl groups...especially a diol..." Thus, in the case of phosphate monomers, the monohydroxy(meth)acrylic acid esters may be substituted for polyols. However, there is no general suggestion that such substitution of polyols may be extended to the preparation of phosphonates. In fact, the process Okada refers to as the "process described above" is specific to phosphate compound preparation.

Specifically, Okada's commentary on the "process described above" begins in column 11, at line 42, and characterizes the process as an esterification of a compound having two or more hydroxyl groups with a (meth)acrylic acid derivative to form a (meth)acrylate compound keeping at least one hydroxyl group (see column 11, lines 54-58). The resulting (meth)acrylate compound keeps at least one hydroxyl group and is subjected to phosphate esterification of the hydroxyl group with a phosphorus oxyhalide (*id.*, lines 58-61). Thus, "the process described above" is limited to phosphate compound preparation.

In summary, the citations referred to by the Examiner in Okada are wholly consistent with the teachings of Billington with respect to the formation of phosphates from reactions of hydroxyl groups with a phosphorus oxyhalide or phosphorus pentoxide. However, because Okada specifically limits the reactions of polyols to the preparation of phosphates, Okada in no way suggests interchangeability of the monohydroxy(meth)acrylic acid esters with polyols for the preparation of phosphonate compounds.

*Even If Okada and Billington Were Combined, the Combination Leads the Skilled Artisan to Phosphates Rather Than to Phosphonates*

Based upon the teachings of Okada and Billington, one of ordinary skill in the art might very well have had reason to combine the well-described phosphate compounds of Okada with those of Billington. As an example, each of the cited references refers to the use of pentaerythritol triacrylate in the preparation of phosphate compounds. However, the preparation of phosphates is the limit of the suggested combination.

Okada isolates any commentary of phosphonate compounds from that of the phosphates discussed in reference. In Okada's description of general and specific procedures for preparation, there is no intermixing of the discussion of phosphates and phosphonates. There is *no* reason evidenced by any reference to have presumed some interchangeability of the compounds employed in the preparative schemes. There is *no* reason that the skilled artisan would have chosen to modify the two phosphonate compounds of Okada. Okada provides only a single

preparative scheme, with no general applicability, and no separate discussion of how phosphonates are to be prepared, apart from specific preparation of compounds 5a and 5b. Compounds 5a and 5b are simply not “lead compounds” that the skilled artisan would have selected for modification with the polyols of Billington.

*Using Okada's Phosphonates As Lead Compounds Is Suggested by The Present Application Only, Not by the Prior Art*

As demonstrated above, Okada and Billington are focused upon the preparation of phosphates, to the near exclusion of phosphonate compounds. The only isolated suggestion of phosphonates is with respect to Okada's compounds 5a and 5b. Absent a contemporaneous rationale for picking them as lead compounds, the Examiner has modified Okada's phosphonate compounds 5a and 5b via contact with the polyol compounds of Billington. The only possible explanation for this choice is that the Examiner has evaluated the Okada phosphonates, *post facto*, in light of the present application and not the prior art.

The present application prepares phosphonates via a reaction between the phosphonate carboxylic acid with an alcohol, thiol, or amine. This reaction is shown by the Applicants to be generally applicable over a wide range of possible starting materials. See paragraph 5. Conversely, Okada forms the phosphonate compounds via a complicated reaction scheme that is singularly described with absolutely no indication that the described procedure is generally applicable. See Okada's examples 5-1 in col. 40 and 8-1 in col. 42. Thus, the limited scope of Okada's phosphonates is not the basis for the selection of a lead compound, but rather, a dead-end with limited applicability. Although, the present application forms a wide general basis, according to the legal precedent outlined above, the present application cannot be the Examiner's impetus for the selection of a lead compound in Okada.

At the most, Okada and Billington provide the person of ordinary skill in the art a roadmap and reason to modify the phosphates of Okada, but no reason at all to modify either of the two phosphonates that are described by Okada. To attribute any broader applicability to

Okada's phosphonates is tantamount to an impermissible hindsight reconstruction, informed by the present application. Further, such an attribution is in conflict with the requirement, per *Eisai* as discussed above, for a reasoned identification of a lead compound. Accordingly, a *prima facie* case of obviousness has not been established, warranting withdrawal of the rejections and allowance of the application.

**(B) Rejoinder of Claims Should Be Effected**

In making final the requirement for restriction, the examiner stated that Balsamo shows a compound of claim 1. Since claim 1 now is free of the art, however, formula (I) embodies a special technical feature that ties together each of the proposed groups of claims. Accordingly, applicants request rejoinder of the Group II and III claims, to issue as well in this application.

**CONCLUSION**

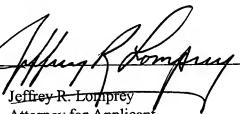
Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Heincer is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.